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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,162	06/04/2001	Jason Koontz	05311-024001	5882

26161 7590 09/06/2005

FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 09/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/874,162

Applicant(s)

KOONTZ ET AL.

Examiner

Karen A. Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 33 is/are allowed.
- 6) ☒ Claim(s) 34 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

1. After review and reconsideration, the finality of the Office action mailed September 10, 2004 is withdrawn.
2. Claims 1-18, 20-31, 35-37 have been canceled. Claim 34 has been amended. Claims 33 and 34 are pending and under consideration.
3. Sections of Title 35, U.S. Code not found in this action, can be found in a previous action.
4. Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to isolated JAZ polypeptides which have a sequence encoded by a nucleic acid molecule having a nucleotide sequence which hybridizes under stringent conditions to a nucleic acid molecule comprising SEQ ID NO:7 or SEQ ID NO:9, said stringent conditions being 6X sodium chloride/sodium citrate at about 45 degrees C, followed by at least one wash in 0.2X SSC, 0.1% SDS at 50 degrees C. Thus the claims encompass variant polypeptides which are encoded from sequences which hybridize to SEQ ID NO:7 and 9. The specification describes three JAZ polypeptides of SEQ ID NO:2, 5 and 8. The specification states that the name "JAZ" refers to "juxtaposed with another zinc finger" and that said polypeptides are expressed from genes expressed as a result of a chromosomal translocation of (7;17) (p15; q21). Thus the instant claims are drawn to mutant gene sequences which are formed as a result of chromosomal breakage and rejoining. The specification describes three such genes. However, the description of said three polypeptides does not describe the relationship between the structure of the polypeptides, or the genes encoding said polypeptides and the structure of any other polypeptides produced from said chromosomal translocation. The general knowledge in the art does not recognize that the structure of one protein expressed as a result of a translocation event does not provide any indications as to the structure of other proteins expressed as a result of the

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same translocation event. The nature of proteins which are up-regulated by being placed into proximity with a promoter by means of a translocation event, or the nature of proteins expressed from new coding sequences formed as a result of a translocation event is that said proteins are variant structures and in the present state of the art, the structure of one does not provide guidance to the structures of others. Further, there is no nexus between the functional significance of the polypeptide of SEQ ID NO:8 and any other variant polypeptide which can hybridize to the nucleic acids of SEQ ID NO:7 or 9. The specification does not provide any limiting definition for a JAZ polypeptide which would require a specific functional attribute to be inherent in said polypeptide. Thus, the claim encompasses polypeptides which differ both in structure and in function from the disclosed polypeptides of SEQ ID NO:2, 5 and 8. One of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of three members of this genus is not representative of the variants of the genus and is insufficient to support the claim.

5. Claim 34 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the JAZ polypeptide of SEQ ID NO:8 and the JAZ polypeptide of SEQ ID NO:8 encoded by degenerate coding sequences, does not reasonably provide enablement for variants of SEQ ID NO:8 which are encoded by nucleic acids which hybridize under the recited stringent conditions to SEQ ID NO:7 and 9. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re wands, 858 F.2d 731, 737.8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claims are drawn to isolated JAZ polypeptides which have a sequence encoded by a nucleic acid molecule having a nucleotide sequence which hybridizes under stringent conditions to a nucleic acid molecule comprising SEQ ID NO:7 or SEQ ID NO:9, said stringent conditions

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being 6X sodium chloride/sodium citrate at about 45 degrees C, followed by at least one wash in 0.2X SSC, 0.1% SDS at 50 degrees C. Thus the claims encompass variant polypeptides which are encoded from sequences which hybridize to SEQ ID NO:7 and 9. The specification describes three JAZ polypeptides of SEQ ID NO:2, 5 and 8. The specification states that the name "JAZ" refers to "juxtaposed with another zinc finger" and that said polypeptides are expressed from genes expressed as a result of a chromosomal translocation of (7;17) (p15; q21), but the claim has no limitation as to the function of the claimed variants. The specification describes three JAZ polypeptides which can be used as markers for chromosomal translocations. However, the specification does not teach how to use polypeptides which are encoded by nucleic acids which hybridize to SEQ ID NO:7 and 9, but which do not serve as markers for chromosomal translocation. It is noted that paragraph 1 of 35 U.S.C. requires that one of skill in the art be able to both make and use the instant polypeptides without undue experimentation. However, beyond the polypeptide of SEQ ID NO:8, one of skill in the art would need to establish the functional significance of the variant polypeptide in order to use said polypeptide. Further, if one of skill in the art were subject to screening for other polypeptides which were markers for chromosomal translocation and which hybridizes to SEQ ID NO:7 and 9 as claimed, one of skill in the art would be further subject to undue experimentation because of the requirement for screening for variant polypeptides as a marker for chromosomal translocation before conducting the hybridization of the claim. Given the lack of teachings in the specification, one of skill in the art would be subject to undue experimentation to make and use the claimed JAZ polypeptides.

6. All other rejections as set forth or maintained in the previous Office action are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 11 am to 10 pm, except Wed, Fri.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.

8/29/2005


KAREN A. CANELLA PH.D.
PRIMARY EXAMINER